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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			EXAMINER TONGUE, LAKIA J	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/526,884

Applicant(s)

SANDBERG ET AL.

Examiner

LAKIA J. TONGUE

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 12 and 14-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 12 and 14-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's response filed on December 14, 2009 is acknowledged. Claims 11, 14-17, 20 and 24 have been amended. Claims 1-10 and 13 have been cancelled. Claims 11, 12 and 14-24 are currently pending and under examination.

Objections Withdrawn

2. In view of Applicant's amendments, the objection to claims 11 and 13 for the following informalities: 'com- prising' should be comprising and lacking the word "of" between the words concentration and said is withdrawn. The cancellation of claim 13 renders the objection to said claim moot.

Rejections Withdrawn

3. In view of Applicant's amendments, the rejection of claims 11-13, 18, 19, 21, 23 and 24 under 35 U.S.C. 102(b) as being anticipated by Pritikin et al. (U.S. Patent 4,664,861) is withdrawn. The cancellation of claim 13 renders the rejection of said claim moot.

4. In view of Applicant's amendments, the rejection of claims 14, 15, 17 and 20 under 35 U.S.C. 103(a) as being unpatentable over Pritikin et al. (U.S. Patent 4,664,861) is withdrawn. The cancellation of claim 13 renders the rejection of said claim moot.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. The rejection of claims 11, 12 and 14-24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for the reasons set forth in the previous office action. The cancellation of claim 13 renders the rejection of said claim moot. The amendment to claims 11, which was rendered vague and indefinite by the use of the phrase "...a separation matrix with eliminated or reduced microbial content, the method comprising the steps of providing said separation matrix, microbially contaminated", renders the rejection of that claim moot. The amendments and remarks made with regard to the rejection of claims 14-17 and 20, which were rendered vague and indefinite by the use of the terms "g⁻¹", renders the rejection of said claims moot. The amendment to claim 16, which was rendered vague and indefinite by the use of the phrase "propyl paraben is between 0.25 and 0.25 g⁻¹", renders the rejection of said claim moot.

Applicant argues that:

1) Claim 24 is amended to refer to the EP 1997 test protocol.

Applicant's argument has been considered but is deemed non-persuasive.

With regard to Point 1, while an amendment has been made, it is unclear what is meant by said phrase, as it is not explicitly defined by the specification. What

constitutes "EP 1997 test protocol"? The specification remains unclear with regard to which ramifications are associated with fulfilling said test protocol?

As previously presented, claim 24 is rendered vague and indefinite by the use of the phrase "EP 1997 test protocol is fulfilled". It is unclear what is meant by said phrase, as it is not explicitly defined in the specification. What constitutes the "EP 1997 test protocol", which is to be fulfilled? As written, it is impossible to determine the metes and bounds of the claimed invention.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 102/35 USC § 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 11, 12, 14-21, 23 and 24 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Huth et al. (US 2003/0100101 A1; Filing date 6/27/02).

The rejected claims are drawn to a method of producing a separation matrix with eliminated or reduced microbial content, comprising steps of: providing a microbially contaminated separation matrix, in a housing or container; wherein the microbially contaminated separation matrix comprises a polymeric porous material in beaded form, a microfiltration hollow-fiber, or a flat sheet membrane; adding an aqueous antimicrobial preservation composition, which comprises at least one alkyl paraben, to said separation matrix in said housing or container; allowing said aqueous antimicrobial preservation composition to exert its effect in said housing or container until the number of colony forming units per g preservative composition is sufficiently reduced; and rinsing said aqueous antimicrobial preservation composition from said housing or container to provide the separation matrix with eliminated or reduced microbial content.

Huth et al. disclose simultaneous cleaning and decontaminating compositions and methods of making and using them. Huth et al. disclose types of dialyzers to include: (1) coil, which incorporates a membrane in the form of a flattened tube wound around a central, rigid cylinder core, with a supporting mesh between adjacent portions of the membranes; (2) parallel plate, which incorporates a membrane in tubular or sheet form supported by plates in a sandwiched configuration; and (3) hollow-fiber, which incorporates the semi permeable membrane in the form of the walls of very small fibers having a microscopic channel running through them (see paragraph 0018; the Examiner is equating this to the microbially contaminated separation matrix comprising a microfiltration hollow-fiber or a flat sheet membrane). Huth et al. disclose that preservatives may be added to the formulas of the present invention, particularly to a

separate liquid enzyme formula to preserve the solution against contamination from microorganisms such as bacteria, yeasts and fungi. Conventional preservatives such as thimerosal may be employed, as long as they do not interfere with the performance of the cleaning and decontaminating system. EDTA may be employed, with a preferred concentration of 0.05%-0.10% ^{w/v} in the formula requiring preservation. Moreover, Huth et al. disclose that EDTA as well as other common preservatives such as methyl paraben (methyl 4-hydroxy benzoate about 0.1% ^{w/v}) may be employed. Other parabens such as benzyl-4-hydroxybenzoate, ethyl-4-hydroxybenzoate, propyl-4-hydroxybenzoate and butyl-4-hydroxybenzoate can also be employed as preservatives. Preservatives may be used alone or in combination (see paragraph 0123). Huth et al. disclose that the method involves three basic steps: (1) cleaning, (2) dialysis efficacy confirmation, and (3) high-level disinfecting involving soak times long enough to achieve sterilization. The cleaning step involves removing residual blood, organic and cellular material from the blood side and removing dialysate from the dialysate side of the semi permeable membrane (see paragraph 0022). Huth et al. disclose adding propylene glycol to the formulation. Huth et al. disclose that concentrations of glycols between 20% ^{w/v}-70% ^{w/v} are preferred, although lower or higher concentrations may be employed (see paragraph 0086). In view of the 112/2nd above, the method of Huth et al. is identical to the instantly claimed invention; absent evidence to the contrary, the EP 1997 test protocol is fulfilled.

Huth et al. do not specifically disclose the concentrations of methyl paraben (claim 14), ethyl paraben (claim 15), propyl paraben (claim 16), butyl paraben (claim

17), propylene glycol (claim 20), or that sterilization of the antimicrobial preservation composition occurs before it is added to the separation matrix (claim 21).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the amounts of alkyl paraben in Huth et al. because limitations such as the concentration of a paraben, when to sterilize and aqueous antimicrobial preservation, and the time allowed to exert its effect are being viewed as limitations of optimizing experimental parameters and is part of the ordinary capabilities of one skilled in the art. Moreover, the claim would have been obvious because a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art (*KSR International Co. v. Teleflex Inc.*, 550 U.S.-, 82 USPQ2d 1385 (2007)).

Pertinent Prior Art

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Michels et al. (US 2002/0132030 A1).

Conclusion

8. No claims are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business

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Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LJT

3/27/10

/Robert B Mondesi/
Supervisory Patent Examiner, Art Unit 1645